Consommation et Corporations Canada
Consumer and Corporate Affairs Canada

Bureau des brevets
Patent Office

Ottawa, Canada
K1A 0C9

(21) (A1) 2,024,799
(22) 1990/09/06
(43) 1991/07/25
(52) 2-81

(51) INTL.CL.[5] A41D-13/00

(19)(CA) **APPLICATION FOR CANADIAN PATENT** (12)

(54) Multi-Laminar Mouthguards

(72) Adell, Loren S. - U.S.A. ;

(73) Same as inventor

(30) (US) 469,286 1990/01/24

(57) 29 Claims

ABSTRACT OF THE DISCLOSURE

Several embodiments of mouthguards are disclosed. Liners of impression material are disposed in upper and lower troughs of a main body for conformance with tooth impressions. The main body's occlusal wall contains a series of spaced-apart air/saliva ducts extending in a lingual/buccal sense to establish lingual/buccal fluid communication. The liners are joined with the main body by integral connections which extend through holes in the occlusal wall between the two troughs in bridging portions of the occlusal wall that separate the air/saliva ducts. A mouthguard can be made by directly molding liner material onto opposite sides of the main body's occlusal wall. The liner is the same material on the main body but of a lower durometer to form the occlusal wall as a tri-laminar structure which provides unexpectedly superior impact absorption when in use. Further mouthguard embodiments have: a two part main body in which the two parts are exactly identical so that they can be fabricated by the same mold; the main body has internal pockets containing lower durometer material and providing for the attachment of a separate attaching strap; the relative thicknesses of the liner and the main body are varied in particular ways; a bite locator is provided; and the liner forms a significant portion of the buccal wall as a smooth rounded edge.

MULTI-LAMINAR MOUTHGUARDS

Background and Summary of the Invention

This invention relates to mouthguards and their manufacture.

One of the common uses of mouthguards is in contact sports activity where a participant may be subject to impacts that could at times be sufficiently severe to loosen or even dislodge one or more teeth, or to cause damage to facial bone structure. In some activities, the use of mouthguards is mandated, while in others, it is optional. While mouthguards are considered useful in protecting teeth, the use of any particular mouthguard is not a guarantee that injury will be avoided in all cases.

There are different varieties of mouthguards that are presently available on the commercial market. In general, they are mass-produced and come in a limited number of size ranges, often containing instructions for cutting a manufactured size to a shape to more closely fit a particular individual. As such, these mouthguards are not manufactured to conform to the actual teeth impressions of any particular individual.

One type of such commercial mouthguards comprises the use of a material which can be more or less softened by immersion in hot water. When the softened mouthguard is then placed in the mouth and the individual bites onto it, a limited impression of the occlusal surfaces of the teeth of the respective arches may result. In other words, it is only the occlusal surfaces of the mouthguard that provide any conformance at all to the teeth of

the arch, and conformance of lingual and buccal surface of the mouthguard to the lingual, buccal, and interproximal regions of the teeth is not achieved. It is recognized that this type of mouthguard fails to provide as great a degree of protection as a custom-fitted mouthguard, but it is fairly inexpensive and can provide some benefit.

A custom-fitted mouthguard is available usually only through a dentist who takes actual full impressions of the upper and lower arches. The mouthguard is then fabricated by usual procedures from these impressions. While this mouthguard provides a fuller degree of protection, it is considerably more expensive than the mouthguards that are typically mass-produced and sold commercially in athletic stores, variety stores, and the like.

The present invention is directed to a new and improved mouthguard which is suited for mass-production, yet can provide a greater degree of conformance to individual teeth of the arches including not only the occlusal surfaces, but the lingual surfaces, buccal surfaces, and interproximal regions as well. As such, the invention provides an edge guard which can be manufactured at reasonable cost so as to be mass-produced and marketed in athletic stores, variety stores, and the like, yet which can provide many of the benefits that are attainable with much more expensive custom-made mouthguards.

Briefly, the invention in one presently preferred embodiment comprises a one piece body that has a shape that corresponds generally to the upper and lower arches but contains upper and lower liners of impression material that is adapted,

when placed in the user's mouth, to more closely conform to actual impressions of the teeth of the arches such that the arches including occlusal, lingual, buccal surfaces, and interproximal regions are provided with an improved degree of protection. With the selection of suitable impression materials, arch conformance can be achieved at normal body temperatures so that procedures such as the soaking of the mouthguard in hot water beforehand are unnecessary. Moreover, by attention to particular details in the relative proportions of the accommodations in the one piece mouthguard body for the impression material, and the selection and arrangement of the impression material in these accommodations, teeth of the arch can be protected not only just along the occlusal surfaces, but along significant portions of the lingual and buccal surfaces of the teeth including the interproximal regions, even to the gingiva.

The impression material is intended to be permanently joined to the mouthguard body, and certain aspects of the invention relate to the manner of such joining. Hence, many of the benefits of a custom mouthguard can be provided in a relatively low cost, mass-produced mouthguard in accordance with the invention.

A still further feature of the invention is that the basic mouthguard body contains lingual/buccal ducts that provide for fluid communication between lingual and buccal regions of the mouth. This is important when the mouthguard is in use because such ducts can facilitate flow of air and/or saliva.

In addition to details of the preferred embodiment of

mouthguard which will be illustrated in the drawings, there will also be described certain details of the methods for making and using the mouthguards. Unexpected beneficial properties can be obtained in a mouthguard by molding the mouthguard in a particular way. Specifically, I have found that by making the liners of the same but lower durometer material as the main body material, the mouthguard will exhibit a surprising improvement in impact absorption when in use. This attribute has been demonstrated by comparative testing with mouthguards of other construction.

A further aspect of my invention relates to a construction in which the main body of the mouthguard is constructed to provide for internal zones of material that has durometer lower than that of the main body. The inclusion of these lower durometer zones offers the possibility for improved impact absorption and, hence, improved performance. The embodiment of such internal lower durometer zones can be accomplished in any of several unique ways.

One way is by fabricating the main body in two halves, providing one or more pockets in one or both of the two halves at locations where the two halves interface with each other, and filling the pockets with lower durometer material. The filling of the pockets with lower durometer material may be accomplished by means of injecting material into the pockets, or by placing an insert into the pockets before the two halves of the main body are placed together. The insert may be a piece of suitable material or it may be a gel-type, or even fluid, material that is encapsulated within an enclosure such as a sac or bag.

Another aspect of the invention relates to the manner in which the two pieces of the main body are fabricated. In particular, the two halves of the main body can be fabricated as identical parts that can fit together to create the complete main body. This result is obtained in the disclosed embodiment by fabricating locating means in each part that are identical from part to part, but which in each part are complementary in a symmetrical manner in the individual part.

A related aspect of the multi-piece main body construction involves the attachment of an attaching strap when such an attaching strap is desired in the mouthguard. Suitable pocketry can be fashioned in the two halves for acceptance of an attaching end portion of an attaching strap that fits into the pocketry so that when the two halves are placed together, the attaching end portion of the attaching strap is captured between them. The portion of the strap that fits to the main body has a locating means for properly locating the strap with respect to the main body.

A still further feature of the invention relates to the shaping of the mouthguard in certain regions thereof. One improvement involves the creation of a slightly indented area in the occlusal wall of the main body in the molar regions. Another involves the use of the rim of the liner material to form a smoothly rounded rim of a trough's buccal wall; in particular, the rim of the liner material forms a significant portion of the wall containing the trough rim, and its smooth rounded shape promotes wearer comfort.

The foregoing features, advantages, and benefits of the

invention, along with additional ones, will be seen in the ensuing description and claims which should be considered in conjunction with the accompanying drawings. The drawings disclose a presently preferred embodiment of mouthguard according to the best mode contemplated at the present time in carrying out the invention as to details of the mouthguard itself, its method of manufacture, and its use.

Brief Description of the Drawings

Fig. 1 is a front perspective view of a mouthguard embodying principles of the invention.

Fig. 2 is a top plan view of the mouthguard of Fig. 1.

Fig. 3 is a perspective view looking generally in the direction of arrow 3 in Fig. 2.

Fig. 4 is an enlarged transverse cross-sectional view taken generally in the direction of arrows 4-4 in Fig. 2.

Fig. 5 is a cross-sectional view taken generally in the direction of arrows 5-5 in Fig. 4.

Figs. 6-11 are transverse cross-sectional views similar to the view of Fig. 4 illustrating different transverse cross-sections.

Fig. 12 is a partial top view of a posterior portion of a mouthguard.

Fig. 13 is a lingual view of Fig. 12.

Fig. 14 is a buccal view of a mouthguard.

Fig. 15 is a perspective view from the rear right side showing the main body of the mouthguard.

Fig. 16 is a view similar to Fig. 15 showing the

completed mouthguard.

Fig. 17 is a side lingual view.

Fig. 18 is a cross-sectional view taken approximately along line 18-18 in Fig. 16.

Fig. 19 is a cross-sectional view taken approximately along line 19-19 in Fig. 16.

Fig. 20 is lingual perspective view relating to the fabrication of another embodiment of mouthguard according to the invention.

Fig. 21 is a view taken in the direction of arrows 21-21 in Fig. 20.

Fig. 22 is a fragmentary elevational view of a portion of Fig. 20.

Fig. 23 is a sectional view taken in the direction of arrows 23-23 in Fig. 21.

Fig. 24 is a sectional view taken in the direction of arrows 24-24 in Fig. 21.

Fig. 25 is a view in the same direction as Fig. 20 showing the completed embodiment.

Fig. 26 is a sectional view taken in the direction of arrows 26-26 in Fig. 25.

Fig. 27 is a sectional view taken in the direction of arrows 27-27 in Fig. 26, but with the main body being omitted.

Fig. 28 is a sectional view taken in the direction of arrows 28-28 in Fig. 26.

Fig. 29 is a view in the same direction as the view of Fig. 21, but relating to another embodiment.

Fig. 30 is a sectional view taken in the direction of

arrows 30-30 in Fig. 29.

Fig. 31 is a sectional view taken in the direction of arrows 31-31 in Fig. 29.

Fig. 32 is a fragmentary perspective view relating to a further embodiment.

Fig. 33 is a sectional view relating to a tri-laminar configuration.

Fig. 34 is a sectional view relating to another multi-laminar configuration.

Fig. 35 is a fragmentary sectional view of a modification.

Fig. 36 is a fragmentary sectional view of another modification.

Fig. 37 is a perspective view relating to yet another embodiment.

Fig. 38 is a view taken in the direction of arrows 38-38 in Fig. 37.

Fig. 39 is a view looking in the direction of arrow 39 in Fig. 38.

Fig. 40 is a fragmentary perspective view partly in cross-section.

Fig. 41 is a view in the direction of arrow 41 in Fig. 40.

Fig. 42 is a view of an attaching strap for use with a mouthguard.

Fig. 43 is a view illustrating the manner of attaching the attaching strap to a mouthguard.

Fig. 44 is a plan view of the bottom half of the main

body of Fig. 43.

Description of the Preferred Embodiment

Figs. 1-5 illustrate a first embodiment of mouthguard 20 according to principles of the invention. The mouthguard comprises a body 22 whose shape corresponds generally to that of the upper and lower arches. Disposed on body 22 are liners of impression material 24, 26, respectively, for the upper and lower arches.

Body 22 may be considered to comprise an occlusal wall 28 that bridges intermediate portions of a lingual wall 30 and a buccal wall 32. As such, body 22 forms an upper trough 34 for the upper arch and a lower trough 36 for the lower arch. The respective liners of impression material 24, 26 are disposed in the respective troughs 34, 36.

The impression material that comprises liners 24 and 26 is sufficiently pliable to enable it to conform to the actual impression of the arches when mouthguard 20 is placed in the mouth and bitten upon. The occlusal surfaces of the teeth exert forces toward the occlusal wall 28, and the impression material conforms in such a manner that the liners are also caused to have impressions of the lingual and buccal surfaces of the teeth of the arches including the interproximal regions, whereby, an actual impression of the teeth of the arch is obtained in each liner.

The occlusal wall 28 provides support for the occlusal portions of the impressions, while the lingual and buccal walls provide support of the impression material for obtaining the

impressions of the lingual and buccal surfaces of the teeth of the arches including the interproximal regions. The drawings are representative and it is to be appreciated that the actual amount of impression material that is disposed in a trough is in a suitable amount and arrangement in the trough so that the desired impressions are obtained. The particular mouthguard 20 has an anterior-posterior extent sufficient for the full upper and lower arches.

A further feature of mouthguard 20 resides in the inclusion of air/saliva ducts 38 that extend through the three walls 28, 30, and 32 between the exterior buccal surface 40 and the exterior lingual surface 42. Ducts 38 provide fluid communication between lingual and buccal regions of the mouth that are beneficial for conveyance of air and/or saliva when the mouthguard is in use. This is a convenience in promoting comfort to the user. The embodiment of mouthguard 20 contains a number of such ducts 38 distributed around the extent of the mouthguard. It is to be understood that this is merely a representative illustration and that the size, shapes, and numbers of such ducts may be selected as desired for any particular mouthguard.

As can be seen in Figs. 4 and 5, each duct 38 is bounded by four wall surface portions 44, 46, 48, and 50. These wall surface portions are, in fact, part of the occlusal wall 28 but they extend through the lingual and buccal walls 30 and 32 to the exterior surfaces 40 and 42. Depending upon the particular nature of material used for body 22 and the relative proportions of the ducts and walls, the occlusal wall 28 may be subject to a certain amount of collapse when the mouthguard is bitten. The

amount of such collapse may be controlled according to the particular design of the mouthguard. It is desirable, however, that full collapse be avoided because that would then block the ducts, thereby, defeating their intended purpose.

Fig. 6 illustrates a transverse cross-section 52 through a mouthguard in which like reference numerals are used to designate parts that correspond to those parts already identified for mouthguard 20. The principal difference in the transverse cross-section of Fig. 6 resides in the relative proportions. The lower trough 36 is generally shallower while in the upper trough the lingual wall is shorter than the buccal wall. The impression material liners 24 and 26 line the full extent of the trough as in mouthguard 20.

Fig. 7 illustrates a further cross-section 54, and its several parts are identified by numerals corresponding to those already used in connection with the parts of mouthguard 20. In certain respects, the body of cross-section 54 is similar to that of cross-section 52 of Fig. 6. The primary difference between cross-section 54 and cross-section 52 is that the impression material liners do not line the full extent of either trough 34 or 36 in Fig. 7. Liner material is applied generally in the corners of the troughs so that a central region of the occlusal wall is void of impression material. This enables the user to bite directly into the occlusal wall material, but there is a sufficient amount of impression material suitably organized and arranged in the respective troughs so that the impression material still conforms to the lingual and buccal surfaces of the teeth of the arches including the interproximal regions. Once

again, the particular amount and disposition of impression material in any given mouthguard is designed to provide a desired degree of contact with the teeth of the arch.

Fig. 8 illustrates another transverse cross-section 56 in which the reference numerals correspond to those previously used for corresponding parts of mouthguard 20. In the cross-section of Fig. 8, the mouthguard body 22 comprises two separate parts 22A and 22B. The part 22A contains the buccal wall 32 and an adjoining portion of the occlusal wall 28. The part 22B contains the lingual wall 30 and an adjoining portion of the occlusal wall 28. Thus, the two portions of the occlusal wall 28A, 28B are separated by a small gap 58.

In the embodiment of Fig. 8, the liner is one piece still comprising the upper and lower troughs conforming to the upper and lower troughs 34, 36 cooperatively defined by the two body parts 22A and 22B, but the central regions of the occlusal surface portions of the upper and lower impression material liners 24, 26 are joined by an integral connection 60 that passes through gap 58. In this embodiment, the impression material fills both of the troughs 34 and 36, although the lower trough 36 is illustrated as being somewhat shallower than the upper trough 34. Although not specifically illustrated by Fig. 8, it is possible that the body 22 could be of one piece construction rather than two separate pieces by having bridging portions spanning gap 58 at certain intervals around the mouthguard. In such an embodiment, the gap 58 would not be a continuous gap extending fully around the mouthguard but rather would be a series of individual gaps, or holes, that are separated by the

bridging portions.

Fig. 9 illustrates a further cross-section 62 in which like reference numerals are used to designate parts that have been identified in previous drawing figures. The cross-section of Fig. 9 is basically similar to that of Fig. 8 except that the lingual and buccal walls are omitted from the lower trough 36. The impression material, however, still is fully disposed in covering relation to the lower side of the occlusal wall 28 so that it will receive the impression of the lower teeth when the mouthguard is put to use. The embodiment of Fig. 9 is illustrated as comprising for body 22, the two-part construction 22A, 22B with the one part liner comprising the integral connection 60 passing through gap 58. It is to be appreciated that in a modified form of Fig. 9 (not illustrated), gap 58 could be made a series of shorter gaps rather than one continuous gap, by the inclusion of bridging portions spaced apart around the mouthguard body.

Fig. 10 illustrates a further transverse cross-section 64 of mouthguard in which like reference numerals are used to designate corresponding parts from the previous views. The cross-section 64 is, perhaps, most similar to the cross-sections that are illustrated in Figs. 4 and 6. It differs, however, in that it comprises a series of integral connections 60 for joining the upper impression material liner 24 with the lower impression material liner 26. The embodiment 64 is a cross-section of a mouthguard that incorporates ducts 38, and the gaps 58 are formed as passages which extend through the bridging portions 66 that separate adjacent ducts 38.

Hence, the upper and lower impression material liners are integrally joined by a series of integral connections 60 passing through the series of gaps 58.

Moreover, the liners are interlocked in the respective troughs through the use of interlocking lips 68, 70 in the case of the upper trough and lips 72, 74 in the lower trough. The upper trough lips 68 and 70 comprise crevices 76, 78 within which some of the impression material is disposed. There is also impression material on the opposite side of each lip where the teeth of the arch are disposed when the mouthguard is put to use. In the case of the lower trough lips 72 and 74, the lips simply overhang the edges of the impression material liner.

Fig. 11 represents a further transverse cross-section 80 that is similar to the cross-section of Fig. 10 except that it omits the lips 68, 70, 72, and 74.

Fig. 12 is a fragmentary plan view of a posterior portion of one side of a mouthguard which illustrates the layout of the ducts 38 and the gaps 58. It also shows two dot dash lines 82 and 84, respectively, which are intended to illustrate where a mouthguard, as manufactured, may be cut if, as manufactured, it has too great a posterior extent to fit a particular arch. Cutting across the line 80 will remove the posterior portion, and cutting along the line 82 will remove an even larger portion.

Fig. 13 is a lingual view also illustrating the two lines of cutting 82 and 84.

Fig. 14 is a buccal view of another embodiment of mouthguard in which like reference numerals are used to designate corresponding parts previously described in earlier drawing

figures. This embodiment shows that the upper trough may extend the full extent of the arch, whereas, the lower trough will have lingual and buccal walls only along posterior segments of the mouthguard. In other words, the lower trough comprises only the occlusal wall along an anterior portion.

Mouthguards embodying certain aspects of the present invention may be fabricated using any conventional impression material for the liners; for example, urethanes, silicones, or certain types of vinyl are suitable. The body is also of any conventional mouthguard material but, in general, it will be less resilient and less pliable than the impression material of the liners. Here again, the body may be fabricated of materials compatible with the liner and compatible adhesives used to secure the liner and the mouthguard body together as required.

One of the potential drawbacks of using adhesive alone is that the materials must be FDA-approved, and those adhesives which are currently FDA-approved are often lacking in sufficient strength and durability. This is where the invention provides an advantage because of the interlocking features of the liner with the mouthguard body, for example, with reference particularly to Figs. 8-12. By providing mechanical interlocks resulting from the particular organization and arrangement of the liners and the mouthguard body, rather than depending on adhesive alone, the potential difficulties which may result from adhesive loosening will be less significant. It is contemplated that a suitable mouthguard comprising the liners and body could be fabricated without use of any adhesive at all but, in general, it is contemplated that some adhesive may be required. The advantage,

once again however, is that the mechanical interlocking features render the liner less susceptible to separation from the mouthguard body due to failure of adhesives.

It is also contemplated that a technique, such as shuttle molding, may be used for fabricating the mouthguard so that the liner and mouthguard body can intimately bond together during the fabrication process without the use of individually fabricating the liners and mouthguard body and then assembling them together. The concept of shuttle molding is that, for example, the liner is molded to the body of the mouthguard shortly after the mouthguard has been fabricated and while it is still warm.

Another aspect of the invention comprises the use of a different class of materials for the mouthguard body. These materials comprise a different procedure for securing conformance to the person's arches. Such materials are referred to as moisture-cured materials, and moisture-cured polyurethane is a suitable example of such a material for use in the present invention. When the material is uncured, it is in a somewhat gel-like state.

The mouthguard can be manufactured to the aforementioned constructions using such material, but at the conclusion of manufacture, it is promptly packaged into a hermetically-sealed (i.e., vacuum-packed), sterile, moisture-proof package. In such an environment, the material of the mouthguard material remains formable because it is still uncured. At this point, the product may be deemed a mouthguard preform since the liner material is impressionable and teeth have not yet been impressed into it. Mouthguards packaged in this way are shipped through commercial

avenues until ready to be put to use by the individual. For example, it is contemplated that the mouthguards could be packed in suitable packaging, similar to blister-packing, for store merchandising as consumer items.

When the packaged mouthguard is to be used, the person opens the package, removes the mouthguard, and places it in his or her mouth. Since the body of the mouthguard material is, of course, still formable at this stage, it will form to the impressions of the individual's arches when the individual bites onto it. Due to the presence of water in mouth saliva, the material can begin to cure to a stabilized form. However, after suitable forming, it can be removed from the mouth and placed in water to complete the curing process. Hence, this process is somewhat the opposite of that previously described, insofar as the manner of curing is concerned.

Fig. 15 shows the main body 110 which comprises a general U-shape for fitting into the mouth. It is onto this main body 110 that a liner 112 is molded to complete the mouthguard as shown in Fig. 16.

Main body 110 comprises an occlusal wall 114 and troughs 116 and 118 on opposite sides. The troughs are for the upper arch and the lower arch respectively. Trough 116 is fairly deep while trough 118 is quite shallow. There are a series of spaced apart through-holes 120 extending through occlusal wall 114, and in Fig. 15, the rear ends of the mouthguard main body are cut away for illustration. In Figs. 16, 18, and 19, it can be seen that liner 112 has been molded onto main body 110.

Liner 112 lines the full interior of both troughs 116 and

118. The liner material also passes through-holes 120 so that the material that lines trough 116 integrally joins with the material lining trough 118.

The process for making the mouthguard comprises, first, fabricating the main body. In accordance with certain principles of the invention, it is fabricated from a particular molding material of a particular durometer. The particular molding material is ethylene/vinyl acetate copolymer such as that sold commercially under the brand name Elvax. The main body can be molded by any suitable process, but it is desired that the finished main body have a comparatively higher durometer than the liner. For example, a main body with a durometer of 82-1/2 is quite suitable, although it is to be understood that this is just an example.

Liner 112 can be molded directly onto main body 110 by any conventional molding process. Injection molding and transfer molding are examples of processes. By making liner 112 of the same material as the main body, there is a chemical compatibility between the two which enables the liner to directly bond to the main body without the need to use adhesive between individual parts for attachment; yet according to further principles of the invention, the durometer of liner 112 is made relatively lower than that of main body 110, whereby, liner 112 is relatively softer. For example, a durometer of 40 is quite satisfactory, although it may range from 30 to 50 and still produce acceptable results. The particular durometers for the main body and for the liner are attained by conventional formulation procedures.

Because liner 112 is softer than main body 110, the liner

material remains impressionable after it has been molded onto the main body, and this enables the teeth of the arch to be comfortably, yet securely received in the liner when the mouthguard is in use. It is desirable to mold the liner onto the main body while the main body is still warm since this is believed to create a more intimate bonding; however, this may not be essential in all instances since the materials are identical.

The result of the process is that a tri-laminar construction is created for the occlusal wall of the finished mouthguard. This tri-laminar construction comprises the same material (ethylene/vinyl acetate copolymer) forming the occlusal wall, wherein, two layers of lower durometer sandwich a layer of higher durometer. It is this construction that contributes to the surprising impact absorbing properties of the mouthguard that have been documented by laboratory testing. It should be understood that the main body can contain an insert, and the construction of the mouthguard is still considered tri-laminar.

Figs. 20-28 relate to another embodiment of mouthguard 130. This embodiment may be considered to comprise a three-part construction consisting of an upper main body part 132, a lower main body part 134, and a liner part 136. As revealed best by Fig. 29, the completed mouthguard has an upper trough 138 for receiving teeth of the upper arch, and a lower trough 140 for receiving teeth of the lower arch. Liner part 136 lines both troughs 138, 140, with upper main body part 132 forming the upper trough 138, and lower main body part 134 forming the lower trough 140. Each main body part has an occlusal wall portion 142, a lingual wall portion 144, and a buccal wall portion 146. The

occlusal wall portions of the two main body parts are in juxtaposed relation to conjointly form the main body occlusal wall. The two lingual wall portions 144 cooperatively form the lingual wall, and the two buccal wall portions 146, the buccal wall.

In accordance with an aspect of the invention, the two parts 132, 134 are identical and, therefore, are capable of being fabricated in the same mold. The completed mouthguard is fabricated by juxtapositioning the occlusal wall portions of the two parts 134, 136 and then molding the liner part in place directly onto the assembled parts 134, 136 so as to form a unitary mass that constitutes the mouthguard.

In order to aid in the proper juxtapositioning of the two main body parts, their confronting portions are provided with integral locating means. Furthermore, these locating means are organized and arranged such that the locating means in the upper part is complementary to the locating means in the lower part, and in each individual part the locating means has a pattern that is symmetrically complementary about the medial plane 147 that bisects the mouthguard into right and left halves. Thus, it can be seen in Fig. 21 that there are four connectors, or projections, 148, 150, 152, 153 in the right half of the part and four receivers, or receptacles, 154, 156, 158, 159 in its left half, and that the pattern of the connectors is the mirror-image of that of the receivers about the medial bisector plane.

The confronting sides of the occlusal walls of each main body part contain lingual/buccal slots 160 that are spaced closely to each side of the medial plane so that in the completed

mouthguard, there are two air/saliva ducts 162 at the incisal region. One of the advantages of constructing the main body in two halves is that a less complex, and less expensive, mold is required for creating the air/saliva ducts.

Beyond these ducts 162, the construction further comprises walled regions 164. When the two parts 132, 134 are placed together in juxtaposition, the connectors of each lodge in the receivers of the other, and the edges of the walled regions of one part abut those of the other part. This forms two pockets 166, 168 mesially beyond the air/saliva ducts.

Each part 132, 134 also contains several holes 170 that extend completely through its occlusal wall portion within its walled regions 164. When the two parts are placed in juxtaposition in the manner described in the immediately preceding paragraph, these holes 170 provide communication to the pockets 166, 168. It is at this stage of the fabrication process that the liner part is fabricated onto the mated main body parts 132, 134. The process involves placement of the mated main body parts into a suitably shaped mold cavity, and then injecting the material that is to form the liner into the cavity. The liner material, while fluid, can be injected through-holes 170 to enter and fill pockets 166, 168 while also forming the lining of the troughs. The completed form is presented by Figs. 25-28.

The material of the main body parts 132, 134 is preferably a higher durometer and, therefore, harder material than that of the liner part. For example, about a forty durometer liner and about an eighty-five durometer main body are suitable. EVA is suitable for the material of both the main body

and liner. The finished construction of the mouthguard comprises the liner part serving to interlock with the two juxtaposed main body parts so that the three parts are an integral unit, and the liner part integrates the liner material lining the troughs, the material passing through the holes 170 and the material filling pockets 166, 168.

From a functional standpoint when the mouthguard is in use, the liner material filling the pockets can aid in impact force absorption and dissipation. The effect of the filled pockets is to create a five layer construction for the occlusal wall along the pocket regions as can be seen in Fig. 26. The finished mouthguard also possesses the feature of having the liner material form smooth rounded edges 171 extending along the buccal walls for promoting wearer comfort. (See Fig. 40 also.) Not only do edges 171 have a smooth rounded shape, they also form a structural part of each trough's buccal wall, about one-fourth to one-third of the height of that wall. This constitutes a further inventive feature.

Figs. 29-31 portray a further embodiment of mouthguard 172 which is generally similar to embodiment 130. Accordingly, like reference numerals will be used to designate like features of both embodiments, as well as for ensuing embodiments. The chief difference between the two embodiments 172 and 130 is in the pattern of connectors and receivers and of holes 170. The connectors are in the form of circular male dowels 175 while the receivers are in the form of circular female dowels 177. The dowels are of suitable lengths such that they mate in telescopic fashion when the two main body parts are juxtaposed. The pattern

of holes 170 comprises a total of six holes associated with each pocket. The first and sixth holes of each pocket partially intersect the shorter sides of the generally four-sided pocket wall. Fabrication of mouthguard 172 is accomplished in the same manner as for embodiment 130. The result is a five layer occlusal wall within the pocket regions. It is possible to make the male dowels of tubular shape so that during molding of the liner onto the main body, liner material can pass through the telescoped dowels to provide additional integral joining of the portions of the liner material that are disposed in the troughs. Fig. 29 shows a ridge of essentially the same height as walled regions 164 located between the two slots 160 to comprise a hole 170 so that the two halves of the main body can be integrally united by liner material at the region between the two air/saliva ducts 162.

Fig. 32 presents a construction that differs in the manner in which the pockets are filled. In this construction, a suitably shaped pre-pack 178 is disposed between each of the two pairs of confronting pocket regions prior to the juxtapositioning of the two main body parts 132, 134. The pre-pack 178 has a suitable durometer that may be the same as, or different from that of the liner part 136. The pre-pack contains through-holes 180 that align with the holes 170 so that when the liner part is fabricated onto the pre-pack-containing main body parts, the liner material can pass through the holes 170 and 180 to integrally join the upper trough liner with the lower trough liner. The final result is that the pre-packs are captured within the pockets, and a five layer construction results along

the pocket regions. If the durometer of the pre-packs differs from both that of the liner and that of the main body parts, the five layer construction will feature: 1) two outer layers of the same relatively softer durometer (i.e., liner material) overlying, 2) two layers of the same relatively harder durometer (i.e., main body material) overlying, 3) a single layer (i.e., pre-pack material) of a durometer that differs from those of the other four layers. Of course, the pre-pack layer could be of a durometer that is the same as that of the liner material. The embodiment of Fig. 32 comprises pins 181 integrally formed at the pockets end walls, and the ends of the pre-pack contain suitable accommodations for these pins. Alternatively, these pins could be holes 170 as in Fig. 29 to provide for liner material to pass through during the molding of the liner onto the main body.

Fig. 33 represents an embodiment that omits the pockets so that a tri-layer, or tri-laminar, construction results.

Fig. 34 represents an embodiment in which the pre-pack is in the form of a membrane-encapsulated fluid (air or liquid) or a gel.

Fig. 35 illustrates a further feature that may be incorporated into a two-part main body, but which will result in the two parts no longer being identical. This feature involves constructing the two parts of the main body such that the occlusal wall of the main body has a reduced thickness along its mesial regions 181A (i.e., for the molars) in comparison to its thickness labially of these regions at 183. The overall thickness of the complete occlusal wall of the mouthguard is generally the same throughout so that this construction results

in greater total thickness for the liner material in the labial region than in the molar regions. A desirable embodiment of this construction is represented by Fig. 35 which shows that the main body occlusal wall has its lower surface indented in the molar regions. This can produce a somewhat different characteristic for the finished mouthguard than if the wall had uniform thickness throughout.

A further aspect of this feature is shown by Fig. 36 where the thickness of the occlusal wall of the main body is also reduced along the labial region 185 by making an indentation in the upper surface of the main body along the labial region. This can also produce a different characteristic and, as illustrated in Fig. 36, may be combined with a decreased thickness occlusal wall of the lower main body part along the mesial molar regions 187. Constructions such as those of Figs. 35 and 36 may provide for the creation of better impressions when the mouthguard is put to use by an individual.

Figs. 37-39 present a further feature that may be incorporated into one or both halves of the main body. It comprises the inclusion of pockets 189 into the buccal wall. When the two halves of the main body are assembled for receiving the liner material, the liner material will flow into pockets 189 so that two different durometer materials will be present in the buccal wall of the mouthguard. By so including these buccal wall pockets filled with liner material, the compressive characteristic of the mouthguard along the buccal wall may be made different from that which would exist in a solid buccal wall mouthguard of only main body material. The pockets are created

by suitably designing the mold that is used to fabricate the main body halves. The pockets are open at both the inside of the buccal wall and the occlusal wall, and can be created during molding by use of suitable projections in the mold cavity.

Figs. 42-44 illustrate an embodiment that includes an attaching strap 193, such as is often used in a mouthguard to provide attachment to a helmet's face mask or face bar. The attaching strap is molded as a separate piece (Fig. 42), and the two main body parts 132, 134 are designed for accommodation of the strap. The strap is fabricated of a suitable material, EVA, for example, and preferably has a durometer equal to or slightly less than that of the main body material. The end of the strap that joins with the main body of the mouthguard comprises an arcuately shaped portion 195 that is adapted to fit between opposing pocket portions 197 that are designed into the labial region of the two main body halves. The buccal walls of the two main body parts contain suitable notches 199 that provide for passage of the strap through the buccal wall of the finished main body. As shown by the drawing, it is possible to include holes 201 in the arcuately shaped portion that align with corresponding holes 203 in the occlusal wall portions of the two main body halves, so that when the liner part is molded onto the two main body parts after the strap has been captured between the two halves, liner material will pass through the aligned holes to integrally join the liner material in one trough with the liner material in the other trough. The attaching strap also has a tab 205 that is situated to fit behind the buccal wall of the upper main body half, in the area indicated in broken lines 207 in the

drawing.

Figs. 40 and 41 present an embodiment that incorporates the smooth rounded edge 171 for the upper edge of the upper trough's buccal wall in accordance with principles described earlier. The embodiment of these two Figs. differs from earlier embodiments, in that, it comprises a one piece main body 211 having the upper trough noticeably deeper than the lower trough. Liner material lines the occlusal wall of the main body in both troughs; it also lines the lingual and buccal walls of the upper trough. For the lower trough, however, the shallow nature of the trough essentially precludes any liner covering its lingual and buccal walls. In fact, the lingual and buccal walls of the lower trough are in the form of small ridges of triangular-shaped cross-section as best seen in Fig. 41. These ridges may be considered as chamfers at the internal corners of the occlusal wall with the sides. The numeral 213 designates the somewhat larger buccal ridge and the numeral 215 the somewhat smaller lingual ridge. These ridges, particularly the buccal ridge, form bite locators for the impression of the lower arch. In other words, it aids in centering the mouthguard when the person places it in his or her mouth for impressioning. This feature is, therefore, quite useful.

As appears in certain of the drawing Figs. 20-44, the joint lines between the upper and lower main body halves are exposed in the completed mouthguards. If desired, the liner material could be molded around the walls to cover either one or both of these joint lines at any desired location or locations along the joint lines.

The present invention has, therefore, been shown to comprise a number of features representing improvements in mouthguards. While a presently preferred embodiment of the invention has been disclosed, it should be appreciated that principles are applicable to other equivalent embodiments within the scope of the following claims.

THE EMBODIMENTS IN WHICH AN EXCLUSIVE PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A mouthguard preform comprising a body having at least one trough for an arch, liner material disposed in said trough for securing an impression of the teeth of the arch when deformed by said teeth and, thereby, conforming the mouthguard to the teeth of the arch when the preform subsequently becomes a usable mouthguard; and joining means joining the liner material to said body comprising mechanical interlocking means for mechanically interlocking the liner to the body, in which said interlocking means is disposed at the occlusal wall of the trough and comprises material integral with said liner which extends through one or more apertures through said occlusal wall and interlocks with the side of the occlusal wall opposite the side containing said trough both before and after the teeth of the arch have been impressed in the liner material.

2. A mouthguard preform as set forth in claim 1 in which said interlocking means extends through a series of spaced-apart gaps through said occlusal wall located in spaced-apart bridging portions of said body that separate lingual/buccal ducts extending in a lingual/buccal sense through the occlusal wall to provide lingual/buccal communication.

3. A mouthguard comprising a body that has an occlusal wall containing one or more air/saliva ducts passing in a lingual/buccal sense through the occlusal wall to establish

lingual/buccal communication.

4. The method of making a mouthguard which comprises molding a main body of ethylene/vinyl acetate copolymer having a given durometer into the general shape of a mouthguard, said main body including an occlusal wall having upper and lower surfaces and then molding a liner of ethylene/vinyl acetate copolymer of lower durometer than that of said main body onto said upper and lower surfaces of said occlusal wall such that an upper layer of said liner is molded directly onto and bonds to said upper surface and a lower layer of said liner is molded directly onto and bonds to said lower surface, said upper and lower layers of said liner being tooth-impressionable after the molding and bonding thereof directly onto said upper and lower surfaces, whereby the mouthguard is provided with an integral tri-laminar construction of ethylene/vinyl acetate copolymer for its occlusal wall, wherein said upper and lower layers which constitute two of the three lamina of such integral tri-laminar construction are tooth-impressionable after the molding and bonding thereof directly onto said upper and lower surfaces.

5. A mouthguard comprising a main body having an occlusal wall, liner material lining opposite sides of said occlusal wall and being of the same material as the main body, but of lower durometer, and the liner material being directly bonded to said occlusal wall by being molded directly onto said occlusal wall.

6. A mouthguard as set forth in claim 5 comprising, for said main body, one part which forms an upper trough portion and another part which forms a lower trough portion, and said liner material lining both troughs and also joining the two parts in assembly.

7. A mouthguard as set forth in claim 6 in which the upper trough liner is integrally joined with the lower trough liner by liner material passing through one or more aligned through-holes in occlusal wall portions of the two main body parts.

8. A mouthguard as set forth in claim 7 in which the two main body parts cooperatively define internal pocketry that contains a material of different durometer from that of the main body parts, and the material within said pocketry contains one or more through-holes aligning with one or more of the aligned through-holes in the occlusal wall portions, and liner material that integrally joins the upper trough liner with the lower trough liner passes through the one or more through-holes of the material within said pocketry.

9. A mouthguard as set forth in claim 8 in which the material within said pocketry comprises a sac whose shape conforms generally to that of the pocketry, said sac containing a gel- or fluid-type material.

10. A mouthguard as set forth in claim 6 in which the

two main body parts are exactly identical.

11. A mouthguard as set forth in claim 10 in which each main body part contains locating means in an occlusal wall portion thereof to facilitate juxtapositioning with the other part in assembly relationship.

12. A mouthguard as set forth in claim 11 in which said locating means comprises in each part a pattern of connectors lying to one side of a medial plane bisecting each part and a pattern of receivers lying to the other side of the medial plane that is the mirror-image about the medial plane of its pattern of connectors.

13. A mouthguard as set forth in claim 12 in which each of the two main body parts comprises a walled region forming a pocket such that with the two parts of the main body in assembly relationship, pocketry is cooperatively formed between the two parts.

14. A mouthguard as set forth in claim 13 in which at least some of said connectors and receivers are located in the wall portion of the walled regions.

15. A mouthguard as set forth in claim 13 in which at least some of said connectors and receivers are located interiorly of the wall portion of the walled regions.

16. A mouthguard as set forth in claim 13 in which said pocketry is in the form of two pockets at each molar region.

17. A mouthguard as set forth in claim 6 in which air/saliva ducts are cooperatively formed by the two main body parts when the latter are in assembly relationship.

18. A mouthguard as set forth in claim 6 in which liner material forms from about one-fourth to one-third of the height of the buccal wall of at least one of the troughs as a smooth rounded edge.

19. A mouthguard as set forth in claim 6 in which said two main body parts cooperatively define pocketry at their labial region, and including an attaching strap having one end captured in said pocketry.

20. A mouthguard comprising two main body parts each of which forms a corresponding one of the troughs of the mouthguard, said two main body parts being juxtaposed in assembly relationship at respective occlusal wall portions.

21. A mouthguard as set forth in claim 20 in which each main body part comprises the same identical pattern of locating means that aids in the juxtaposition of the two main body parts at assembly.

22. A mouthguard as set forth in claim 21 in which said

two main body parts comprise walled pocket portions that cooperatively form internal pocketry when the two main body parts are in assembly, such pocketry containing material of different durometer from that of the two main body parts.

23. A mouthguard as set forth in claim 22 including an attaching strap for the mouthguard, said attaching strap being a separate part having one end captured in said main body pocketry.

24. A mouthguard comprising a main body having at least one trough for an arch and liner material lining said one trough, said liner material forming about one-fourth to one-third of the height of a buccal wall portion of the mouthguard as a smooth rounded edge.

25. A mouthguard as set forth in claim 24 in which the other trough forms a bite locator extending fully around said other trough.

26. A mouthguard as set forth in claim 25 in which said bite locator comprises a triangular-shaped edge.

27. A mouthguard comprising a lower trough for the lower arch, liner material lining the occlusal wall of the lower trough, and a bite locator disposed buccally of the liner material, said bite locator having a triangular-shape in cross-section.

28. A mouthguard comprising a main body having an occlusal wall covered by liner material on both sides, both in total having a generally uniform thickness over at least a portion of the mouthguard, said occlusal wall and said liner material having relative thicknesses such that in a certain region of said mouthguard portion, the thickness of the liner on one side of the occlusal wall is greater than that on the other side of the occlusal wall.

29. A mouthguard as set forth in claim 28 in which the lower thickness of the liner material is greater than the upper thickness of the liner material along a molar region of the mouthguard.

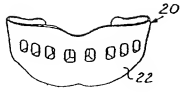

FIG. 1

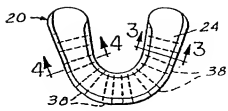

FIG.2

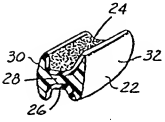

FIG.3

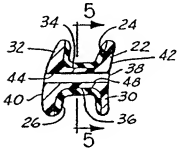

FIG.4

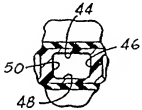

FIG.5

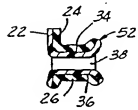

FIG.6

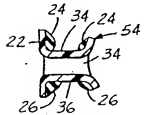

FIG.7

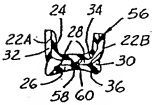

FIG.8

Alex E. MacRae & Co.

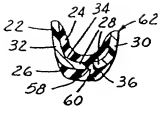

FIG.9

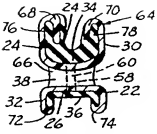

FIG.10

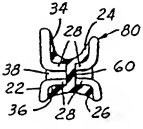

FIG.11

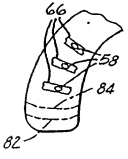

FIG.12

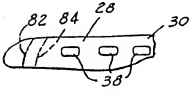

FIG.13

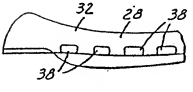

FIG.14

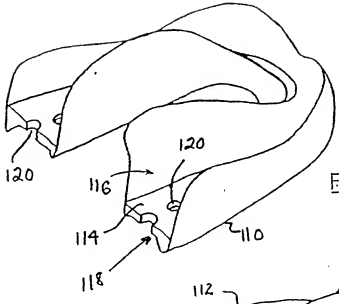

FIG. 15

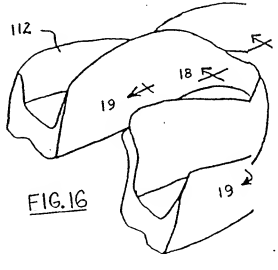

FIG. 16

Alex E. MacRae & Co.

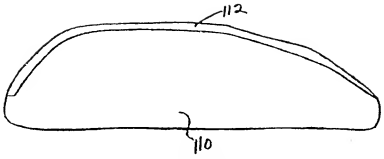

FIG. 17

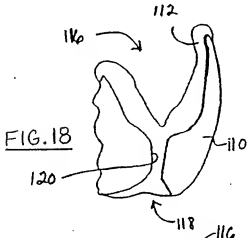

FIG. 18

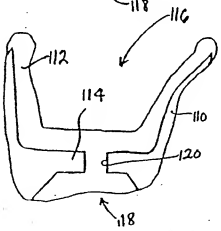

FIG. 19

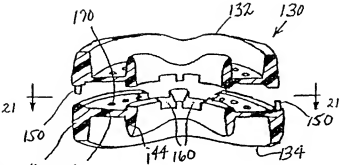

FIG. 20

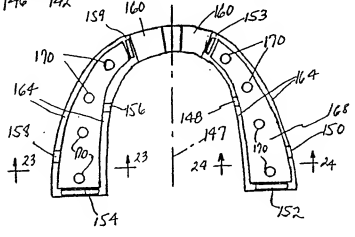

FIG. 21

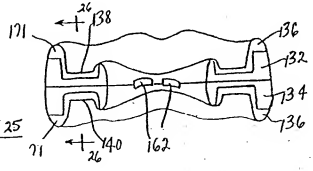

FIG. 25

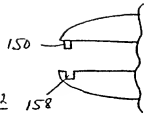

FIG. 22

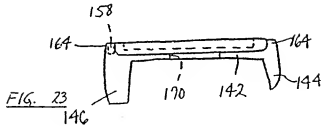

FIG. 23

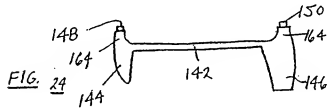

FIG. 24

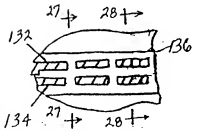

FIG. 26

FIG. 27

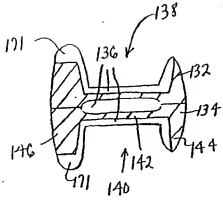

FIG. 28

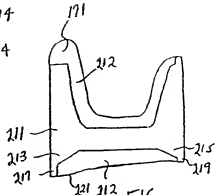

FIG. 41

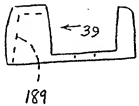

FIG. 38

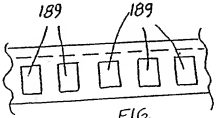

FIG. 39

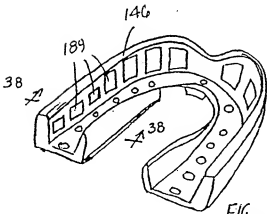

FIG. 37

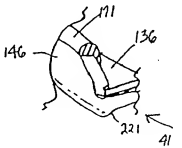

FIG. 40

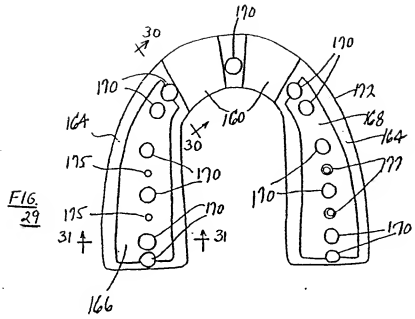

FIG. 29

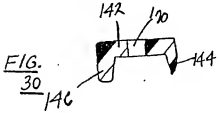

FIG. 30

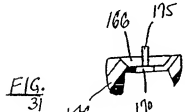

FIG. 31

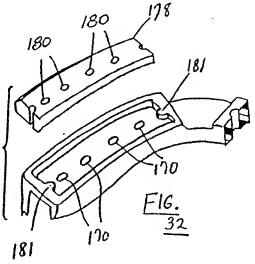

FIG. 32

FIG. 33

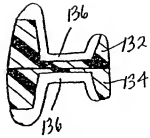

FIG. 34

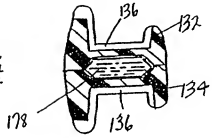

FIG. 35

FIG. 36

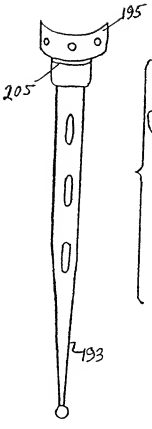

FIG. 42

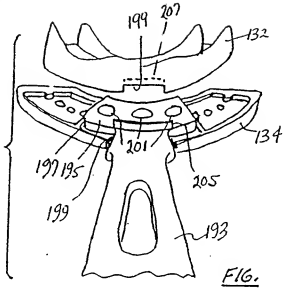

FIG. 43

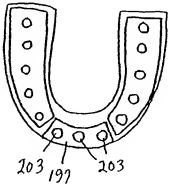

FIG. 44